

Prescribing Controlled Drugs in Addiction Treatment

Section 24 Misuse of Drugs Act
1975

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Introduction

This document provides guidance to help addiction treatment services comply with Section 24 Misuse of Drugs Act 1975 (MODA). Section 24 applies when a medical practitioner prescribes a controlled drug as a treatment for a person's addiction to that or any other controlled drug.

This document has been integrated into the *New Zealand Practice Guidelines for Opioid Substitution Treatment 2014*. The Ministry of Health advises that services read this document alongside relevant best-practice guidance.

1 Operation of Section 24 Misuse of Drugs Act

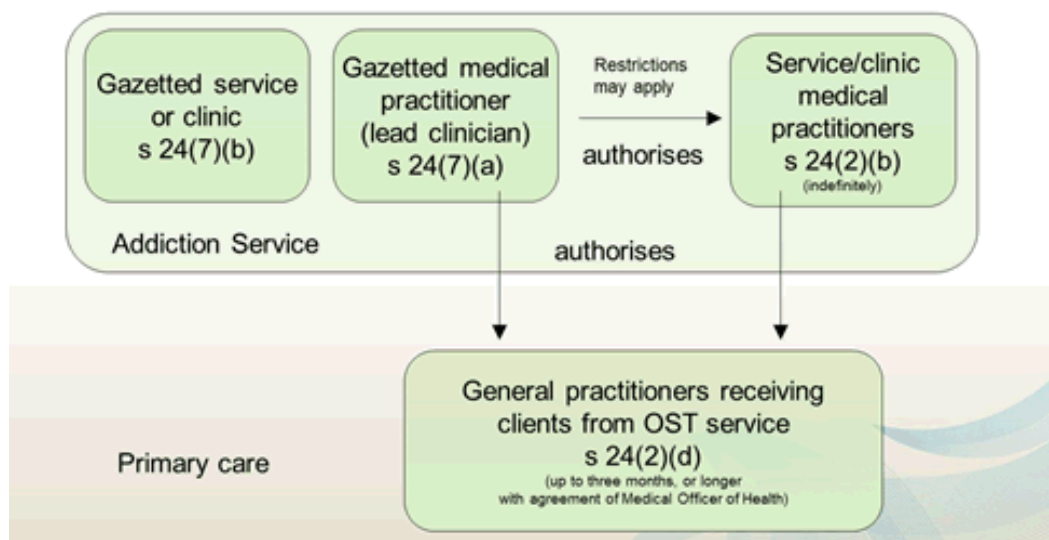
Section 24 MODA governs the prescription of controlled drugs for the treatment of addiction to a controlled drug or drugs.¹ The Minister of Health has the power to specify which medical practitioners and services can prescribe controlled drugs for the treatment of addiction. (Section 24 is reproduced in these guidelines as Appendix 5.)

The Minister can issue a *New Zealand Gazette* notice under Section 24(7) specifying:

- a medical practitioner (s 24(7)(a))
- a service, by listing the clinics and other places constituting that service (s 24(7)(b)).

Typical model for service provision under Section 24 MODA

The following figure describes the intended functioning of Section 24. Within a typical specialist alcohol and other drug (AOD) service, and the service's area of geographical responsibility (typically a district health board(DHB)), only the specialist service and its lead clinician should be specified in the *Gazette*, unless there is a good reason for approving another service and/or medical practitioner. Normally, specialist services are approved under Section 24 to provide opioid substitution treatment (OST).



¹ This publication does not apply to the use of controlled drugs in treating addiction to non-controlled drugs, such as alcohol.

Section 24 envisages a suitable medical practitioner taking clinical leadership of addiction treatment with controlled drugs. This person is specified in a *Gazette* notice, and granted the power to approve other medical practitioners to prescribe controlled drugs for addiction treatment, either within a specified specialist service or in primary care. The clinical lead is responsible for ensuring that any medical practitioner he or she authorises has the knowledge and skills to undertake the tasks delegated to them.

Specialist services must send a copy of all authorities signed by the service's lead clinician (both specialist service medical practitioners under Section 24(2)(b) MODA) and shared care general practitioners (GPs) under Section 24(2)(d) MODA) via email, medicinescontrol@moh.govt.nz, courier or standard post to:

Medicines Control
Provider Regulation
Clinical Leadership, Protection and Regulation
Ministry of Health
PO Box 5013
Lambton Quay, Wellington 6145.

The gazetted lead clinician can approve:

- medical practitioners working within the specialist service indefinitely (Section 24(2)(b) MODA)
- medical practitioners working in primary care (eg, GPs) for up to three months, or longer with the agreement of a Medical Officer of Health (Section 24(2)(d) MODA).

Conditions may be attached to a *Gazette* notice specifying a medical practitioner. These conditions may include, but not limited to:

- the nature of the addiction the medical practitioner can treat
- the particular controlled drugs the medical practitioner can prescribe
- a period of time for which the medical practitioner is approved
- the specified service or services in which the medical practitioner can operate
- limitations or conditions on the medical practitioner's ability to approve other medical practitioners as authorised prescribers.

Alternative forms of service provision under Section 24 MODA

In some areas, someone other than a DHB addiction service organise Section 24 prescribing. Appropriate collaborations between DHBs and primary care providers or non-governmental organisations can be beneficial for consumers of addiction services. They may enhance service provision by creating choice for consumers and improving integration between specialist services and primary care providers.

The Ministry of Health supports discussions among specialist services and primary care providers on innovative ways to improve prescribing for dependence under Section 24 MODA. Emerging arrangements can be supported by *Gazette* notices under these guidelines where appropriate, to ensure that Section 24 prescribing takes place under the clinical supervision of a suitably qualified person. Discussions should initially take place at the local level.

2 Protocol – designation of specialist services

The Director of Mental Health has the power to designate a specialist service under Section 24(7)(b). The Director will designate a specialist service in accordance with the protocol set out below.

1. An appropriate senior staff member within a specialist service such as a clinical leader, service manager, chief executive or other senior manager, fills in an application form (refer to Appendix 2: Application to be specified as an addiction treatment service prescribing controlled drugs for dependence (Section 24(7)(b) MODA) and send it to the Director of Mental Health.
2. The Director assesses the application and determines whether the service is able to give effect to relevant Ministry policies, including:
 - a. *New Zealand Practice Guidelines for Opioid Substitution Treatment 2014* (Ministry of Health)²
 - b. the *Let's get real* framework (Te Pou)³
 - c. relevant service specifications, including the National Health Board's Alcohol and Other Drug Treatment Opioid Substitution Treatment Tier Three specifications.⁴
3. The Director approves or declines the application.
4. If the application is approved, the Director issues a *Gazette* notice.

A designated specialist service has a continuing obligation to comply with relevant guidelines, standards and specifications. If a designated service feels that it may fail to meet the obligations above, a clinical leader or service manager should contact the Director of Mental Health to work through the issue. In some situations the Director may revoke the *Gazette* notice that approved the service.

² Available from the Ministry of Health <www.health.govt.nz/publications>.

³ Available from Te Pou <www.tepou.co.nz/supporting-workforce/lets-get-real>.

⁴ Available through the National Services Framework Library <www.nsfl.health.govt.nz>.

3 Protocol – designation of lead clinicians

The Director of Mental Health has the power to designate a lead clinician under Section 24(7)(a). The Director will designate a lead clinician in accordance with the protocol set out below.

1. A senior clinical leader, chief executive or other senior manager, nominates a lead clinician for a specialist service by writing a letter of recommendation to the Director of Mental Health.
2. The nominee completes an application form (refer to appendix 1: Application to be specified as a medical practitioner prescribing controlled drugs for dependence (Section 24(7)(a) MODA) and the nominee and nominator sign it. A curriculum vitae and appropriate references must be attached to the application form.
3. The Director of Mental Health assesses the application and determines whether the person will be able to meet the lead clinician criteria (see below) and give effect to relevant practice guidelines. The Director consults the Ministry of Health's Medicines Control team as part of this process.
4. The Director approves or declines the application.
5. If the application is approved, the Director issues a *Gazette* notice specifying the lead clinician and any conditions that attach to the approval.

As the Director can attach conditions to the designation of a lead clinician, a *Gazette* notice will normally expire after several years. During the term of the notice, the lead clinician has a continuing obligation to comply with the appointment criteria. If he or she is unable to comply, the Director may not renew the designation, or may revoke it.

4 Departure from appointment protocol

Some established services or medical practitioners may not fully meet the criteria for approval for a number of reasons, including geography, unique service structure and availability of resources. The Ministry of Health continues to support the emergence of novel service structures that can enhance an area's provision of addiction treatment. The Director of Mental Health will therefore consider departures from the protocols described above on a case-by-case basis.

5 Criteria for appointment of lead clinicians under Section 24(7)(a) MODA

The main criteria for medical practitioners to be specified as lead clinicians under Section 24(7)(a) are derived from the following key values for addiction services:

- a recovery focus, which contributes to consumers living full and meaningful lives in the presence or absence of their addiction
- excellent services, focused on safety and the needs of consumers
- respect for consumers and their personal and cultural values
- giving effect to human rights, to protect or enhance a consumer's dignity or mana
- reflecting the importance of relationships with consumers, to support and enhance relationships between consumers and the community.

The Director of Mental Health will consider other relevant criteria on a case-by-case basis.

To be considered for approval as a lead clinician under Section 24(7)(a), a person must be a senior specialist service medical practitioner involved in the treatment of addiction with controlled drugs. At a minimum, they must meet the expectations of specialist service staff outlined in Section 10: The OST workforce and professional development requirements of the *New Zealand Practice Guidelines for Opioid Substitution Treatment 2014* and aim to give effect to all relevant aspects of the *Practice Guidelines* in their service.

Lead clinicians' responsibility for service quality

Lead clinicians should pursue service excellence by:

- promoting best clinical practice
- developing an organisational culture that is focused on a consumer-driven, evidence-informed, collaborative vision
- working with staff to promote a healthy, culturally safe workplace
- advocating for professional development for all staff
- creating and maintaining processes and activities that promote effective supervision, evaluation, coaching and support for all staff
- advocating for sufficient and appropriate resources.

Lead clinicians' responsibility for professional development

Lead clinicians should:

- hold appropriate qualifications and membership in specialist sector organisations
- maintain proficiency in their field by attending and contributing to specialist sector meetings and undertaking continuing education where appropriate.

Lead clinicians' responsibility for consumer focus

Lead clinicians should pursue a culturally appropriate, user-focused service by:

- creating and supporting organisational systems and a culture that is grounded in recovery, including peer support
- promoting and advocating for continuing cultural education, including Māori workforce development
- ensuring that all aspects of the service demonstrate unique Māori perspectives of health and health service delivery
- promoting non-discriminatory practice and implementing policies that examine and challenge stigma and discrimination
- ensuring effective communication with all consumers.

Lead clinicians' responsibility for managing relationships

Lead clinicians should demonstrate the importance of relationships for consumers by:

- creating and participating in community networks of relevant health and social service providers
- promoting and supporting integration between the specialist service and a consumer's primary health care provider, including through a primary health care clinical coordination role
- leading and influencing others in developing positive relationships with whānau, hapū, iwi and communities
- creating and supporting participatory processes that reflect the importance of family, whānau and other social supports to consumers.

6 Operating a specialist service in compliance with Section 24 MODA

Each specialist service prescribing controlled drugs for the purpose of addiction treatment must:

- be an approved service under Section 24(7)(b) MODA
- employ a lead clinician approved under Section 24(7)(a) MODA.

A medical practitioner does not become authorised to prescribe controlled drugs for addiction treatment by virtue of being employed by an approved service. Every medical practitioner prescribing controlled drugs for addiction treatment must be either:

- approved as a lead clinician under Section 24(7)(a) MODA
- working in an approved service and authorised by the lead clinician under Section 24(2)(b) MODA or
- working in primary care, in a relationship with the approved service, and authorised by the lead clinician or an authorised specialist service medical practitioner under Section 24(2)(d) MODA.

Medical practitioners working within an approved service

A lead clinician can authorise any medical practitioner working within an approved service to prescribe controlled drugs for addiction treatment. This authorisation can last indefinitely, but in practice the lead clinician should review the authorisation regularly.

An authorised practitioner should as a minimum meet all of the criteria in Section 10.2: Workforce training and professional development of the *New Zealand Practice Guidelines for Opioid Substitution Treatment 2014*. Regular review of the practitioner's approval should involve an assessment of the practitioner's professional development, including continuing education and participation in appropriate clinical networks.

Specialist services must send a copy of all authorities signed by the service's lead clinician for any specialist service medical practitioners (s24(2)(b)) under Section 24 MODA to Medicines Control.

Medical practitioners providing hospital care

A client can be treated with controlled drugs for addiction in hospital, for a maximum of three days, under Section 24(9)(b) MODA. A hospital clinician treating a client for addiction with controlled drugs should notify the specialist service within three days of initiating treatment. The specialist service must then determine the most appropriate way to engage or re-engage with that client.

Gazetted or approved specialist service medical practitioners can authorise a hospital medical practitioner to continue to treat a client with controlled drugs in the interim if necessary, under Section 24(2)(d) MODA (refer to appendix 4: Authority for a general practitioner to prescribe controlled drugs for the treatment of addiction contains a format for letters granting GP authorities that can also be used for hospital medical practitioner authorities).

7 Supporting consumers in primary care in compliance with Section 24 MODA

Authorising medical practitioners working in primary care

General practitioners accepting transfer of a client from a specialist service to primary care can continue to prescribe controlled drugs to treat the client's addiction with the authority of the lead clinician or an approved medical practitioner working in the service.

A GP authority must be in writing in the format provided in Appendix 4: Authority for a General Practitioner to prescribe controlled drugs for the treatment of addiction (Section 24(2)(d) MODA). This form must clearly state the scope of the authority, the client to whom the authority applies, the controlled drug to be prescribed and any dispensing or monitoring arrangements.

Services must send a copy of each GP authority to the dispensing pharmacy and to the Medicines Control team at the Ministry of Health. The information sent to each should be exactly the same, to ensure client safety and continuity of care in all events.

A GP authority may be granted where the GP:

- holds a current practising certificate that has never been revoked
- has not been the subject of a notice under Section 23 MODA prohibiting him or her from prescribing controlled drugs
- has not been the subject of a notice under Section 58 Medicines Act 1981
- has a suitable combination of experience, education and specialist service support in treating clients dependent on controlled drugs
- agrees to comply with relevant guidelines.

Specialist services have a responsibility to support GPs to whom they grant authority. They should regularly communicate with GPs about specific clients, and provide them with information about safety and best practice when prescribing controlled drugs to treat addiction. GPs must be able to:

- discuss management problems with specialist service clinicians
- request specialist reviews of clients when necessary
- transfer clients back to specialist services when necessary.

Normally, a lead clinician should grant a GP authority. However, if the lead clinician is not available or it is not practicable for him or her to grant approvals, any specialist service medical practitioner with appropriate approval from the lead clinician can issue a GP authority.

Period of GP authority

Subsections (3) and (5) of Section 24 MODA limit the period of a GP authority to three months. This can only be extended with the agreement of the Medical Officer of Health within the Ministry of Health's Medicines Control team.

The policy of Medicines Control is to allow for six-month GP authorities where a service and lead practitioner can demonstrate safe and effective compliance with these guidelines and other relevant documents. To request consideration of a six-month GP authority, a lead practitioner should write a formal letter of request to the Medical Officer of Health in Medicines Control, explaining why a longer period is justified.

The Medical Officer of Health can be contacted by writing to:

Medical Officer of Health
Medicines Control
Provider Regulation
Clinical Leadership, Protection and Regulation
Ministry of Health
PO Box 5013
Lambton Quay
Wellington 6145

Alternatively, email:

medicinescontrol@moh.govt.nz

Appendix 1: Application to be specified as a medical practitioner prescribing controlled drugs for dependence (section 24(7)(a) MODA)

This form should be used by medical practitioners when applying to be able to prescribe controlled drugs for dependence under Section 24(7)(a) Misuse of Drugs Act 1975.

Name of addiction treatment service

Name of nominee

Position

Postal address

()

Telephone

()

Fax

Email address

Additional information

Please attach the following information to your application:

- A letter of nomination from a senior clinical leader or an executive officer
- A letter of application detailing your qualifications, work experience, clinical leadership experience and training in opioid substitution treatment
- A curriculum vitae and copy of current practising certificate
- At least two supporting references
- Evidence of continuing education and/or research in medication-assisted recovery and membership in appropriate professional organisation(s) such as:
 - Section of Addiction Psychiatry within the Royal Australian and New Zealand College of Psychiatrists (RANZCP)
 - Australasian Chapter of Addiction Medicine (AChAM) in the Royal Australasian College of Physicians (RACP)
 - National Association of Opioid Treatment Providers (NAOTP).

Referees

Please give the names and contact details of at least two referees for the Director of Mental Health to contact.

Name:

Contact
details:

Referee 1 details

Name:

Contact
details:

Referee 2 details

Agreement

I (the nominee) agree:

1. to adhere to the *New Zealand Practice Guidelines for Opioid Substitution Treatment* (Ministry of Health 2014)
2. to a review of my status as an approved medical practitioner from time to time
3. that I have not been the subject of a Gazette notice under Section 23 Misuse of Drugs Act 1975
4. that I have not been the subject of a Gazette notice under Section 48 Medicines Act 1981
5. to advise the Ministry of Health of medical practitioners whom I authorise to prescribe controlled drugs for the treatment of dependence under Section 24(2)(b), (c) and/or (d) Misuse of Drugs Act 1975
6. that I will ensure that staff (including authorised prescribers) involved in opioid substitution treatment undertake relevant training and supervision to meet the minimum levels expected in the practice guidelines.

Nominee signature

Nominator signature

Print name

Print name

Date

Date

Appendix 2: Application to be specified as an addiction treatment service prescribing controlled drugs for dependence (Section 24(7)(b) MODA)

This form should be used by an addiction treatment service when applying to be able to prescribe controlled drugs for dependence under Section 24(7)(b) Misuse of Drugs Act 1975.

Name of addiction treatment service

Name of applicant	Position
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Postal address of service

()	()
Telephone	Fax

Email address

Clinic and staffing information

Please provide the street address of each clinic in your service and information about the makeup of clinical staff in each clinic (this includes, but is not limited to, case workers, kaimirimiri, nurses, psychiatrists and other medical practitioners, psychologists, pharmacists and social workers).

Clinic address	Clinician/qualification	FTE
Clinic 1		
Clinic 2		
Clinic 3		
Clinic 4		
Clinic 5		
Clinic 6		

Additional information

Please attach the following information to your application:

- a letter of application
- relevant protocols and procedures your service has in place to demonstrate compliance with the *New Zealand Practice Guidelines for Opioid Substitution Treatment* (Ministry of Health 2014) if applying to be an opioid substitution treatment service
- if necessary, application forms for the gazetting of medical practitioners under Section 24(7)(a) Misuse of Drugs Act 1975.

General agreement

I agree that:

1. our service will adhere to the *New Zealand Practice Guidelines for Opioid Substitution Treatment* (Ministry of Health 2014)
2. our service protocols and procedures are in keeping with the practice guidelines
3. our service complies with the Health and Disability Services (Core) Standards (NZS 8134:2008)
4. our service will collect and forward such statistical data as required by the Ministry of Health
5. our service will notify the Director of Mental Health of our staff composition (including prescribers responsible to this service) every six months.

Treatment programmes

I agree that:

1. each client will receive a written treatment plan that has been agreed between themselves and our service
2. each client will have an assigned case worker
3. our staff will seek not only to minimise the harms of opioid use but also, within the resources available, to normalise the lives of consumers
4. our staff will be trained in HIV and hepatitis issues
5. our organisation will have due regard for cultural and/or gender preference
6. our staff will undertake relevant training to meet the minimum training levels outlined in the practice guidelines
7. our clinical staff (including doctors) will undertake clinical supervision on a regular basis from suitably experienced and qualified people
8. our service has a protocol for the management of pregnant women using opioids.

Ministry of Health requirements

I agree that:

1. the Director of Mental Health will independently review our service as required
2. our service will provide the Director of Mental Health with any required information (eg, reports).
3. the Director of Mental Health will review this authority from time to time.

Applicant signature

Print name

Date

Revocation of this authority

This authority expired because [insert reason]

on [insert date]

[Insert signature]

Lead clinician

cc. **Service Register**
Medicines Control (medicinescontrol@moh.govt.nz)

Authority for a general practitioner to prescribe controlled drugs for the treatment of addiction (section 24(2)(d) MODA)

This form should be used by a lead clinician when authorising a general practitioner (GP) to prescribe controlled drugs for dependence under Section 24(2)(d) Misuse of Drugs Act 1975.

I, _____ [name of medical practitioner], _____ [specialist service], authorise:

GP name

GP practice

to prescribe controlled drugs for the treatment of addiction to:

Consumer name

NHI

Consumer address

The conditions of this authority are set out below.

<p>[Specify general or particular conditions of authority including, where relevant:</p> <ul style="list-style-type: none">• the particular controlled drug• consume of premises• takeaway dose(s)	<p>[insert drug and dose] [insert days and pharmacy] [insert days]</p>
--	--

This authority expires on _____ [date].

Signature

Date

[Medical practitioner]

[Specialist service]

cc. [GP]

[Dispensing pharmacy]

Consumer file

Medicines Control, Ministry of Health, PO Box 5013, Wellington

(medicinescontrol@moh.govt.nz)

Example

<p>Specify general or particular conditions of authority including, where relevant:</p> <ul style="list-style-type: none">• the particular controlled drug• consume of premises• takeaway dose(s)	<p>Methadone 70 mg daily Monday/Wednesday/Friday at Radius Care Pharmacy Tuesday/Thursday/Saturday and Sunday</p>
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Appendix 5: Section 24 Misuse of Drugs Act 1975

24 Treatment of people dependent on controlled drugs

- (1) Every medical practitioner commits an offence who prescribes, administers, or supplies a controlled drug for or to a person who the practitioner has reason to believe is dependent on that or any other controlled drug, –
 - (a) in the course or for the purpose of the treatment of the person for dependency; and
 - (b) otherwise than in accordance with subsection (2).
- (1A) Every midwife or designated prescriber commits an offence against this Act who prescribes, administers, or supplies a controlled drug for or to a person who the midwife or prescriber has reason to believe is dependent on that or any other controlled drug, in the course of, or for the purpose of, the treatment of the person for dependency.
- (2) In the course or for the purpose of the treatment for dependency of a person who the practitioner has reason to believe is dependent on that or any other controlled drug, a medical practitioner may prescribe, administer, or provide a controlled drug for or to the person if the medical practitioner –
 - (a) is for the time being specified under subsection (7)(a); or
 - (b) is –
 - (i) working in an institution, clinic, or place for the time being specified under subsection (7)(b); and
 - (ii) for the time being authorised in writing to prescribe controlled drugs by a medical practitioner working in that institution, clinic, or place who is for the time being specified under subsection (7)(a); and
 - (c) is –
 - (i) acting in the medical practitioner's capacity as a medical officer employed by a hospital care operator within the meaning of Section 58(4) of the Health and Disability Services (Safety) Act 2001 for the time being specified under subsection (7)(b); and
 - (ii) for the time being authorised in writing by the person in charge of that institution, acting under the general or specific directions of a Medical Officer of Health, to prescribe controlled drugs; or
 - (d) is acting –
 - (i) with the permission in writing, given in relation to that particular person, of a medical practitioner for the time being authorised by paragraph (a) or paragraph (b) or paragraph (c) to do so; and
 - (ii) during the period, and in accordance with the terms and conditions (if any), specified or imposed in the permission, or in any written modification of the permission, given by that medical practitioner.
- (3) Except with the concurrence of the Medical Officer of Health, no permission under subsection (2)(d) may specify a period longer than 3 months.

- (4) A permission under subsection (2)(d) may from time to time be renewed by the person who gave it, or any other medical practitioner authorised by that paragraph to give such a permission.
- (5) Except with the concurrence of the Medical Officer of Health, no renewal under subsection (4) of a permission under subsection (2)(d) may be for a period longer than 3 months.
- (6) An authority or permission given or renewed under subsection (2) or subsection (4) –
 - (a) may at any time be withdrawn by the person who gave or renewed it, by written notice to the person to whom it was given; and
 - (b) is deemed to have been withdrawn when, as the case may be, –
 - (i) the notice under subsection (7)(a) specifying the medical practitioner by whom the authority or permission was given is revoked; or
 - (ii) the notice under subsection (7)(b) specifying the institution, clinic, or place, in respect of which the authority or permission concerned was given or renewed is revoked; or
 - (iii) the medical practitioner by whom the authority or permission was given dies, or ceases to work in the premises, clinic, or place to which the authority relates.
- (7) The Minister may from time to time, by notice in the *Gazette*, –
 - (a) specify any medical practitioner (by name) as a medical practitioner who may, subject to any general or specific conditions imposed by the Minister on the recommendation of the Director-General of Health, prescribe, administer, or supply controlled drugs for the purposes of this Section:
 - (b) specify (by name or description) as a place at which controlled drugs may be prescribed, administered, or supplied for the purposes of this Section –
 - (i) any hospital care institution within the meaning of Section 58(4) of the Health and Disability Services (Safety) Act 2001; or
 - (ii) any clinic, or other place in which a medical practitioner for the time being specified under paragraph (a) works.
- (8) The Minister may from time to time, by notice in the *Gazette*, revoke or amend a notice under subsection (7).
- (9) This Section does not apply to –
 - (a) the treatment of a patient, within the meaning of the Alcoholism and Drug Addiction Act 1966, while the patient is in an institution, within the meaning of that Act;
 - (b) the emergency treatment of a patient in a hospital care institution within the meaning of Section 58(4) of the Health and Disability Services (Safety) Act 2001, for a period not exceeding 3 days;
 - (c) the treatment of any restricted person within the meaning of Section 25.